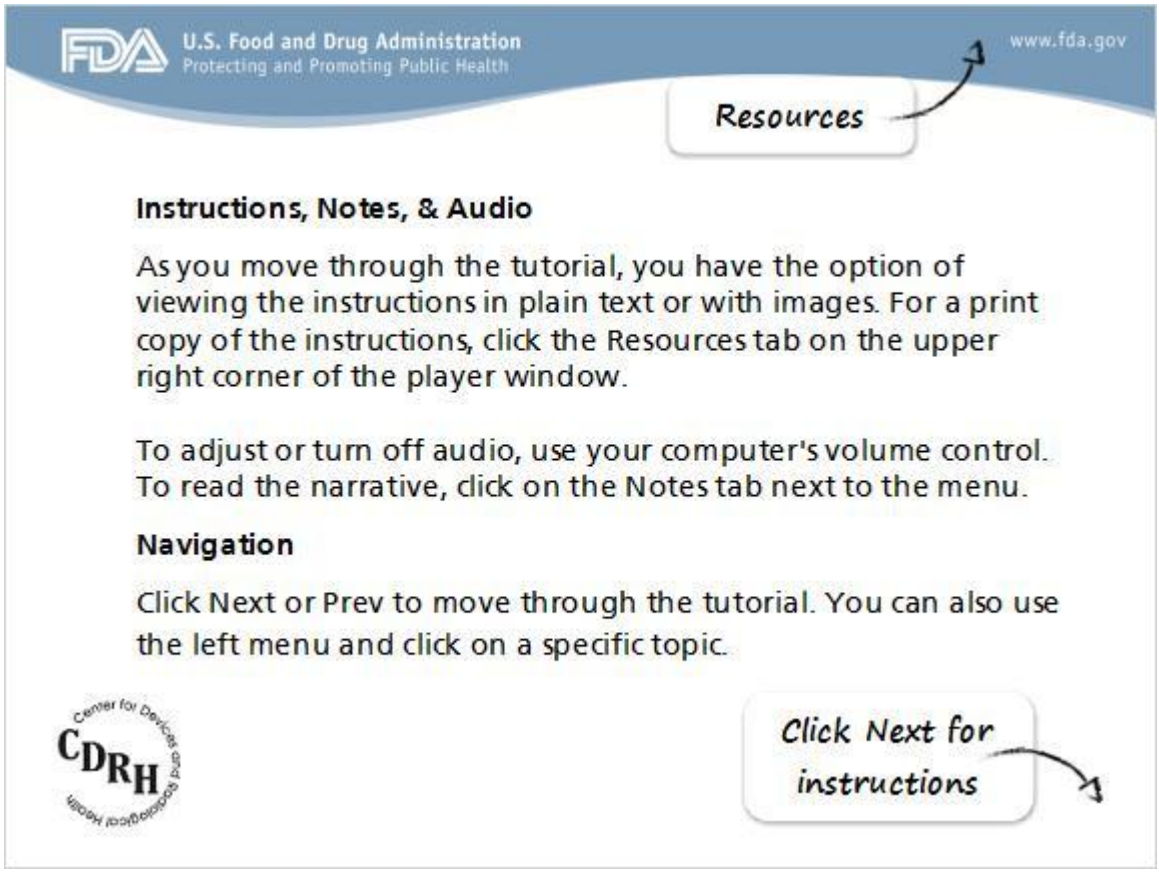
Welcome

Notes:

This tutorial will show you how to complete the annual registration of a medical device facility.

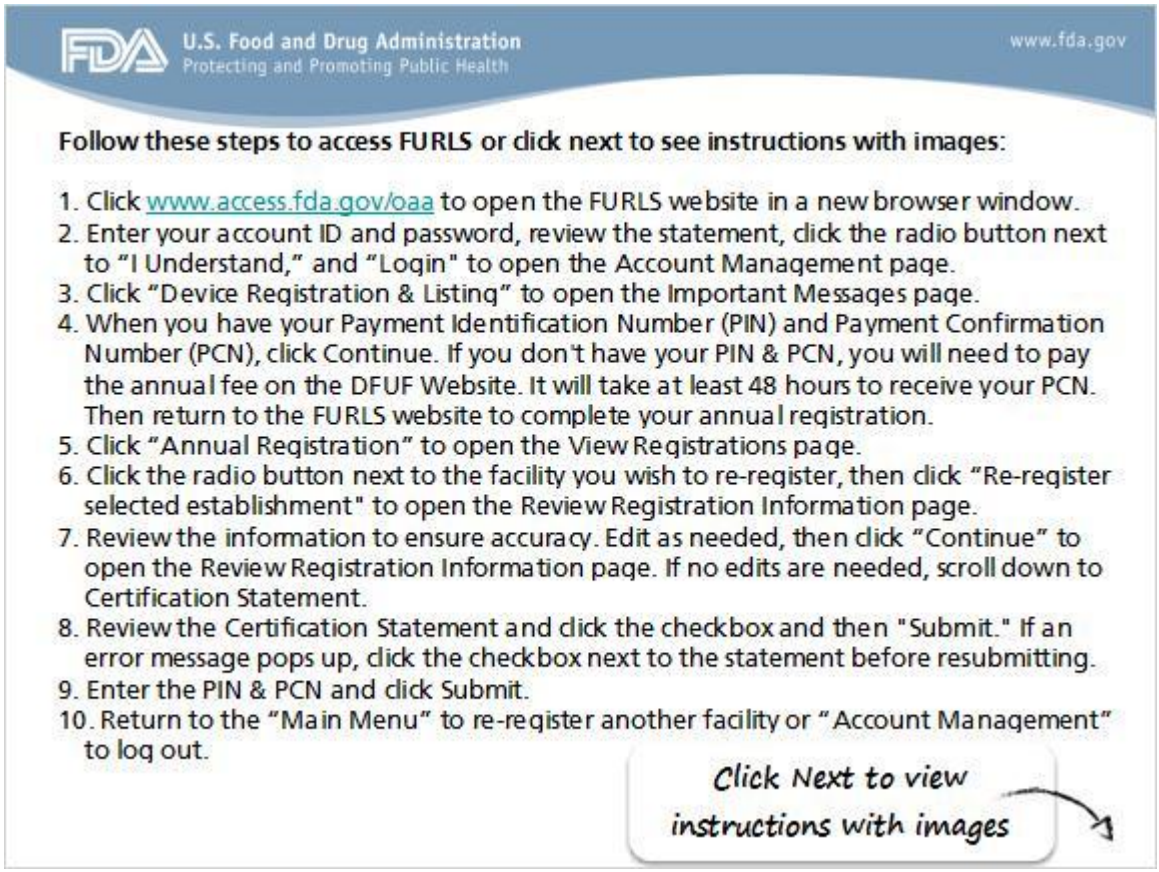
Navigation



Notes:

You have the option of viewing the instructions in text or with images in this tutorial. You can also print the instructions by clicking Resources located in the upper corner of the slide.

Instructions



Notes:

You can start here with the text instructions, or click next to view instructions with images.

Login

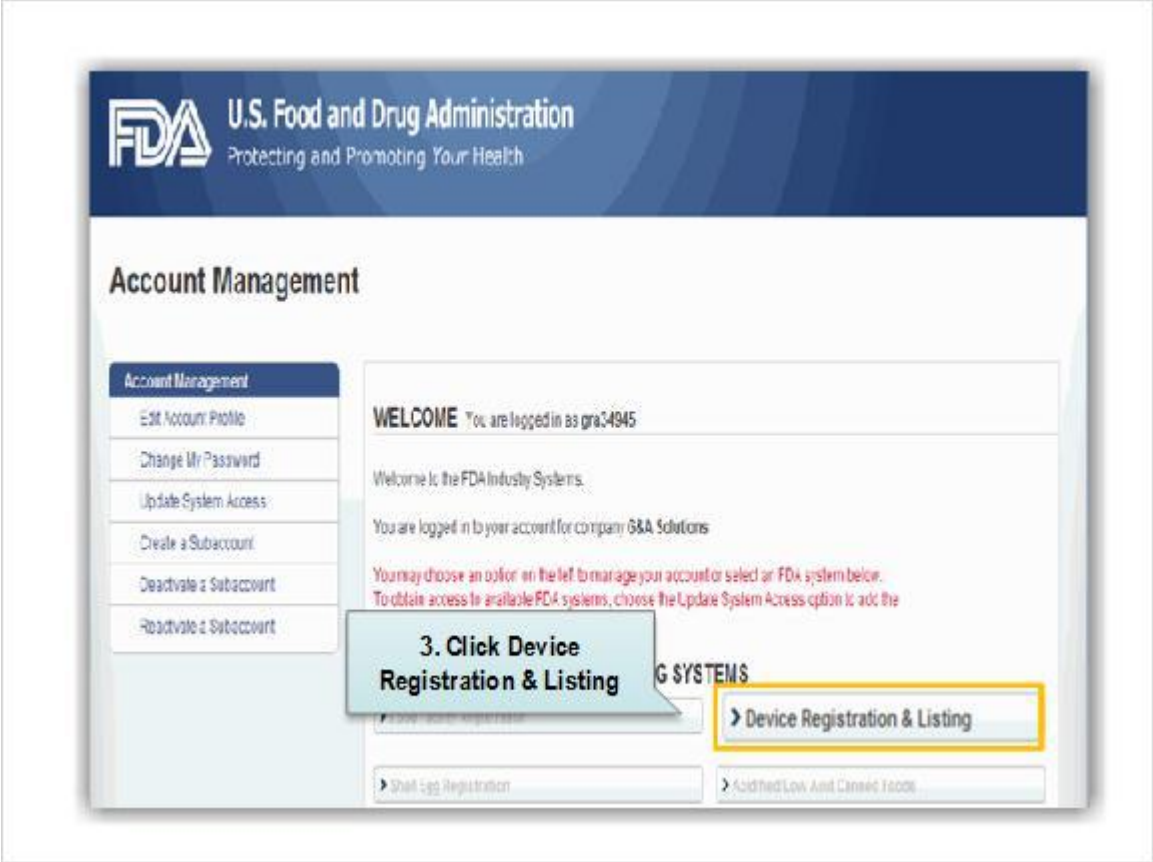
Notes:

For best results, review these instructions with the FURLS website open in another browser window.

1. Go to www.access.fda.gov/oaa to open the FURLS login page.

2. Enter your Account ID & password for the facility that is being registered, then click the radio button next to "I understand" and "Login."

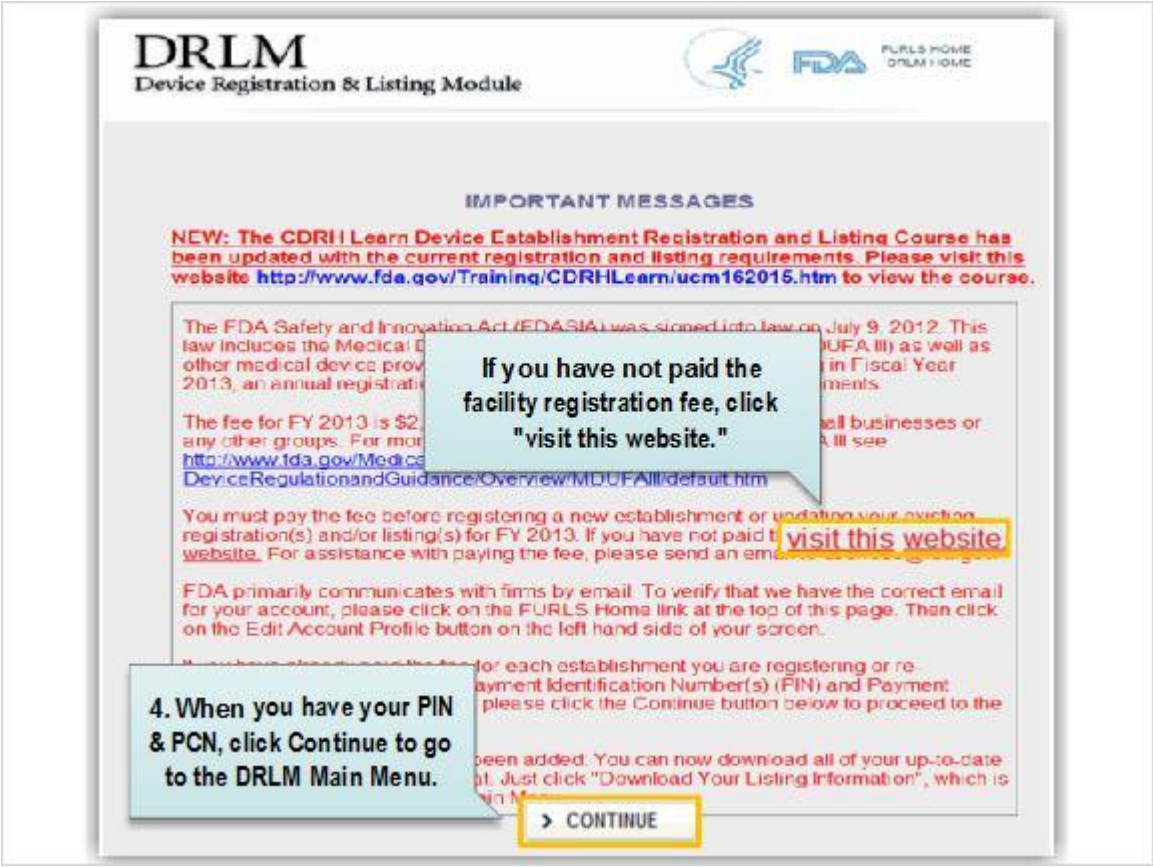
Login



Notes:

3. On the Account Management page, click "Device Registration & Listing" to open the Important Messages page.

Login



Notes:

If you have not paid the annual registration fee, you will not be able to complete the annual registration. You will need to click “visit this website” to open the DFUF Website. After you have received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN), return to the FURLS website to complete your annual registration. Note that it takes at least 48 hours to receive an email with the PCN.

4. When you have your PIN & PCN, click "Continue” to open the DRLM Main Menu.

DRLM Main Menu

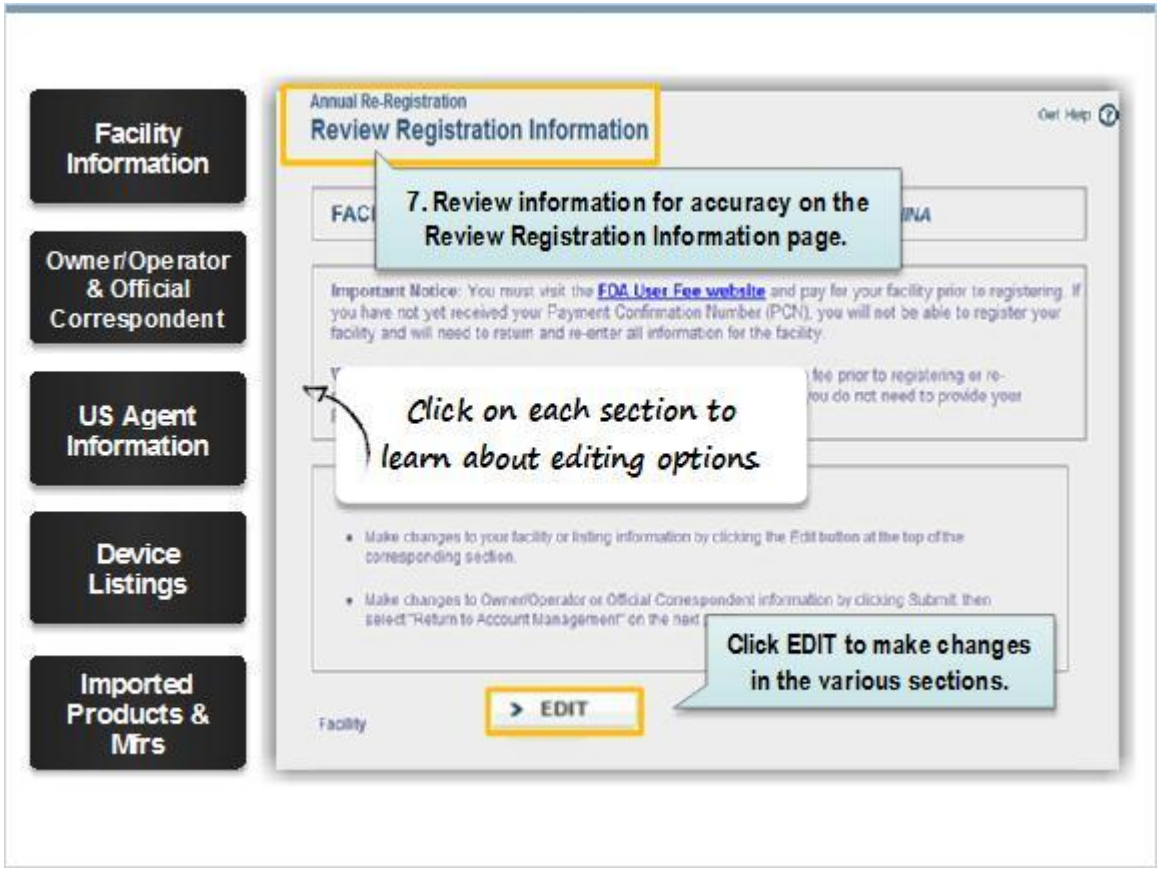
Notes:

5. On the DRLM Main Menu page click "Annual Registration" to open the DRLM View Registration page.

6. On the View Registrations page, click on the radio button next to the facility to re-register, then click Re-register Selected Establishment to open the Review Registration Information page.

Note: If the facility that you want to select is visible but the radio button is grayed out, you will need to contact the owner/operator contact person and ask to be assigned as the official correspondent. If the facility is missing from the page, return to the DRLM main menu and click “view your registration and listing information” to ensure the annual registration was completed. If the facility is not listed, contact the CDRH Registration and Listing Helpdesk.

Editing



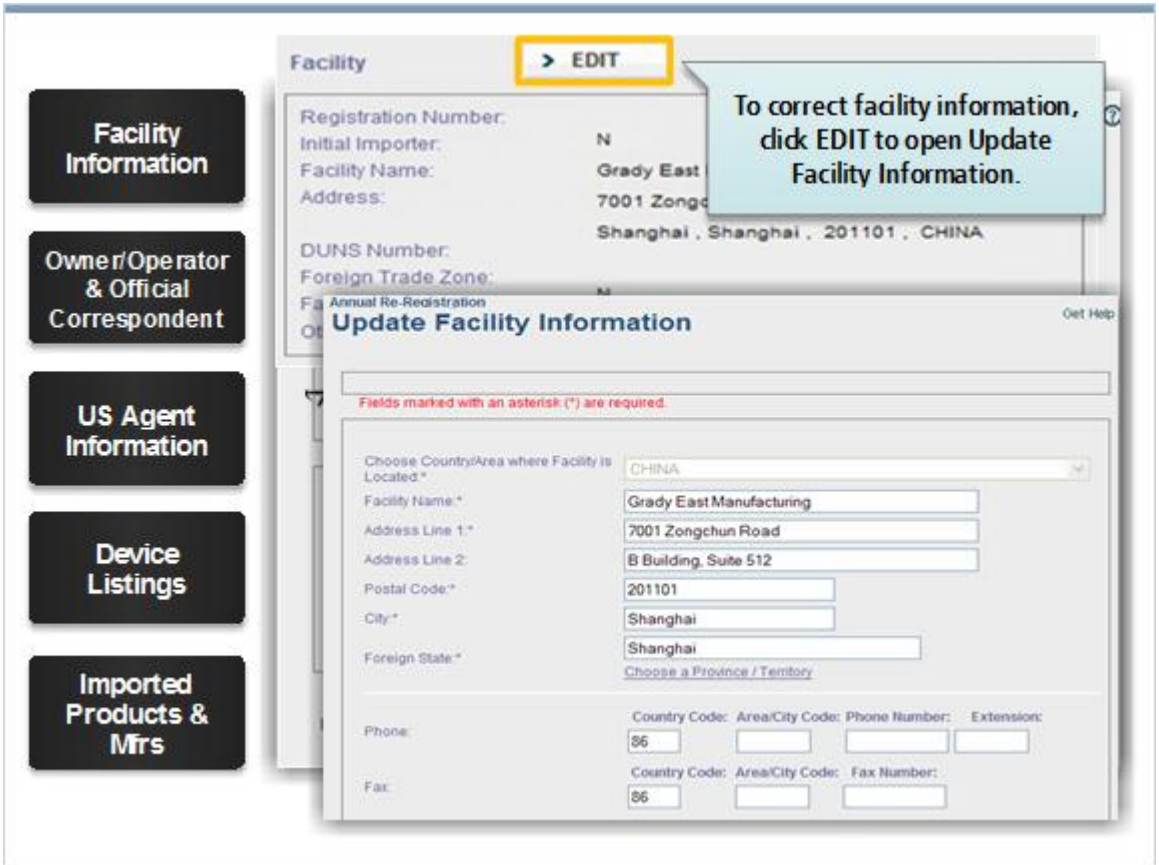
Notes:

7. You have a number of editing options to update information. To learn more about editing each section, click on the topic buttons.

Click "EDIT" on each section to edit the specified information.

Click "Continue" when you are done editing to go back to the Review Registration Information page and scroll down to the Certification Statement.

Facility Information



Notes:

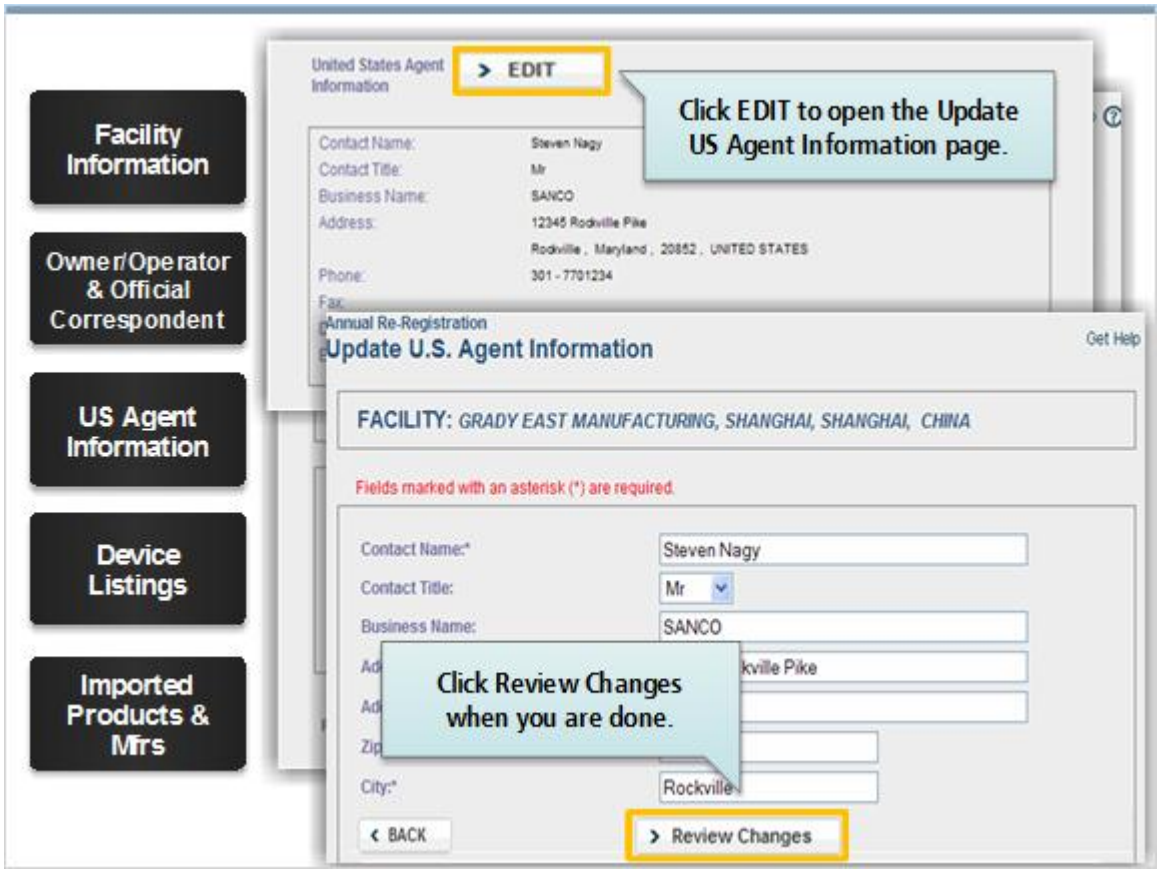
Facility Information: Click "EDIT" to update facility information. However, if the country/area needs editing, you will need to contact the CDRH Registration & Listing Helpdesk.

Owner/Operator and Official Correspondent

Notes:

Owner/Operator Information & Official Correspondent Information: Instructions for how to edit this information is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm#11. After editing, you will need to start the registration process from step #3.

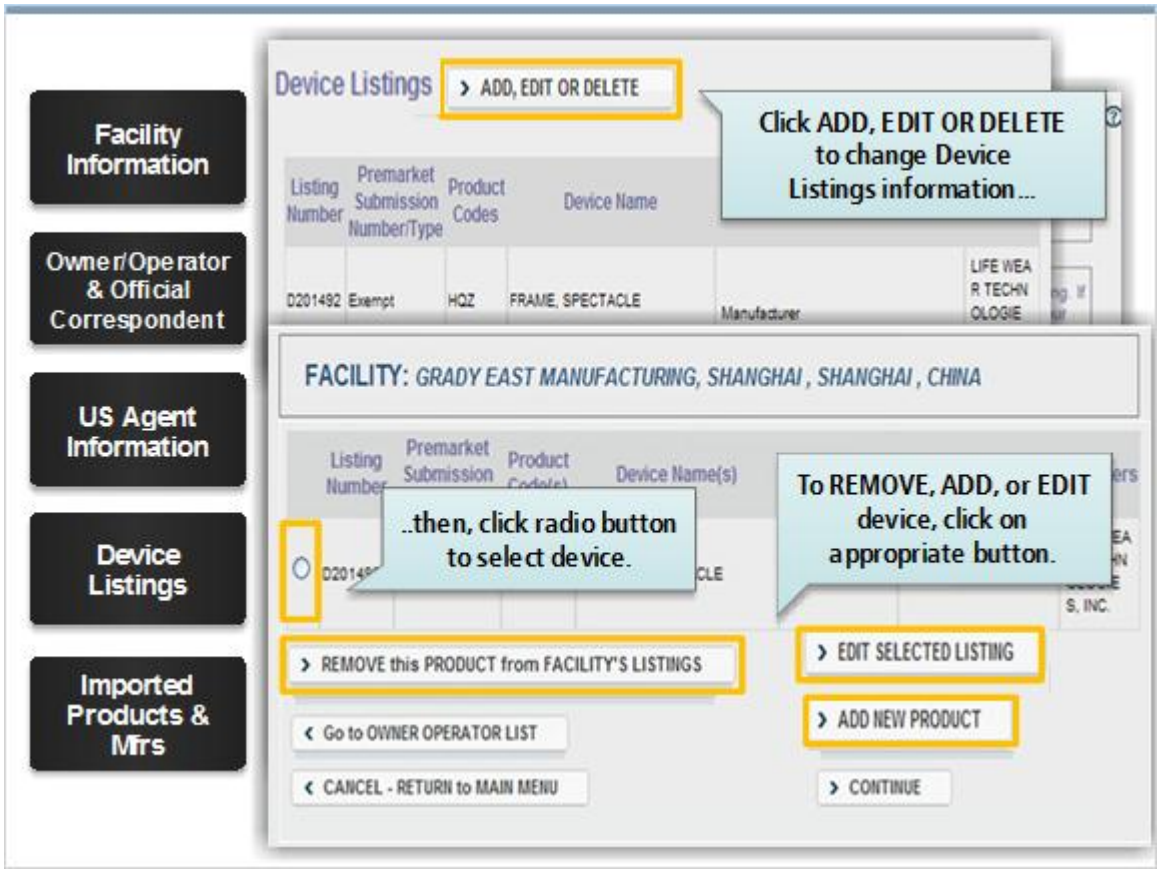
US Agent



Notes:

US Agent Information: Click "EDIT" to change information on the Update US Agent Information page. When you are done, click "Review Changes" to make sure your changes are correct.

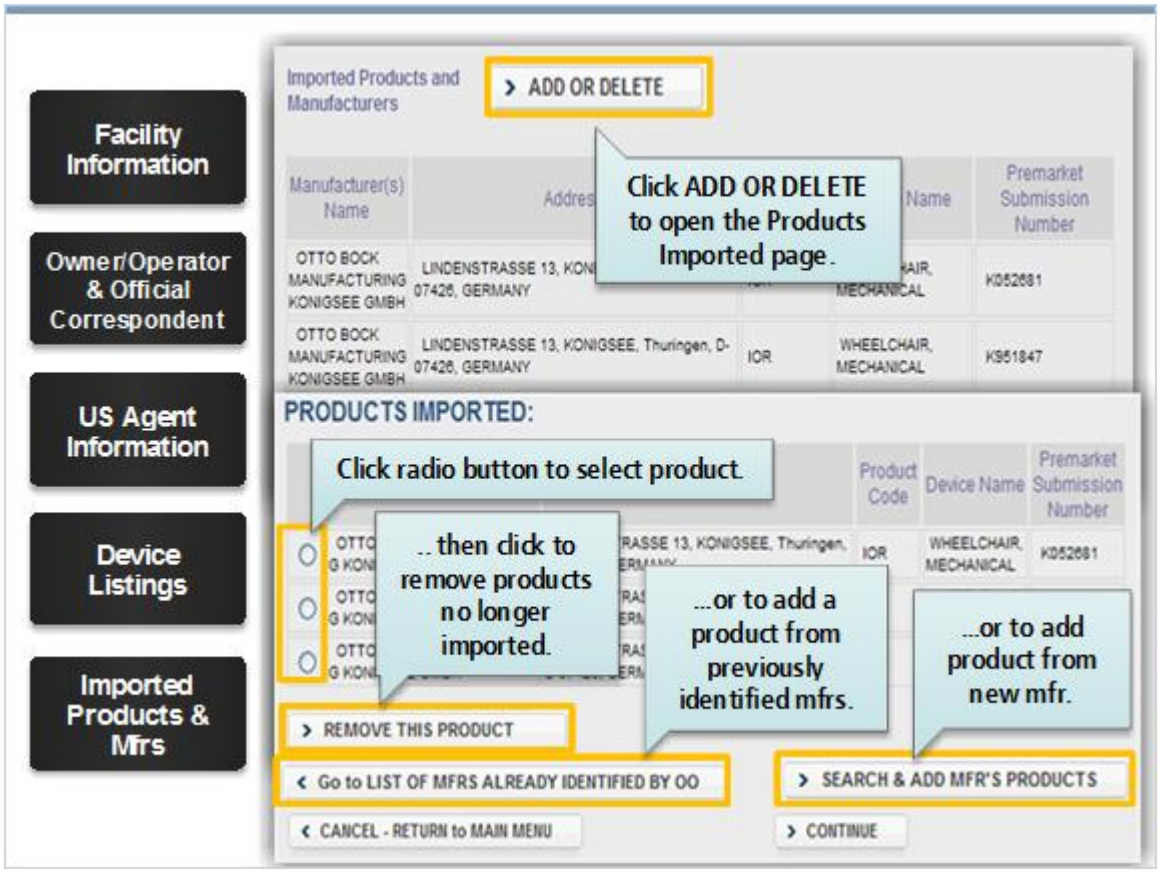
Device Listings



Notes:

Device Listings: Click the radio button to select the device that needs updating. Then click "add, edit or delete" to add, remove or edit device information.

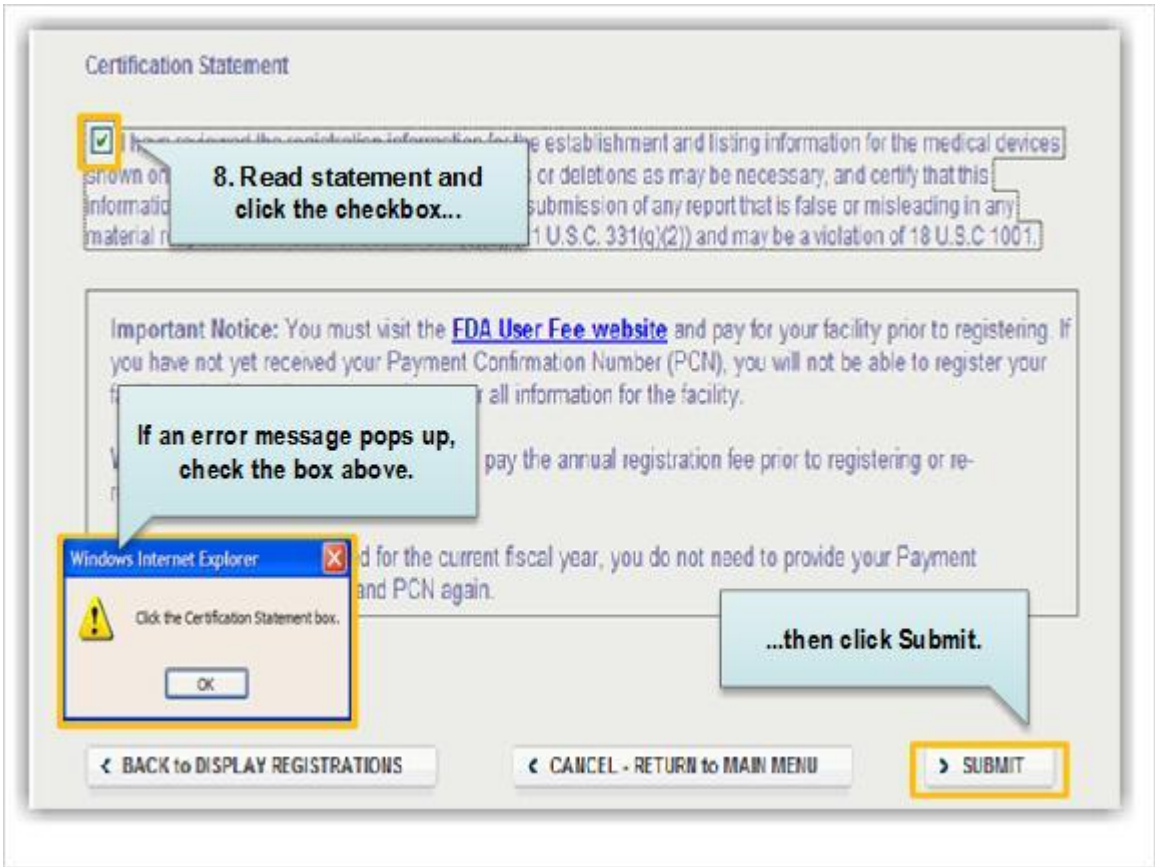
Imported Products



Notes:

Imported Products and Manufacturers: Click “ADD OR DELETE” to remove products that are no longer imported, to add a product from a list of previously identified manufacturers, or add a product from a new manufacturer.”

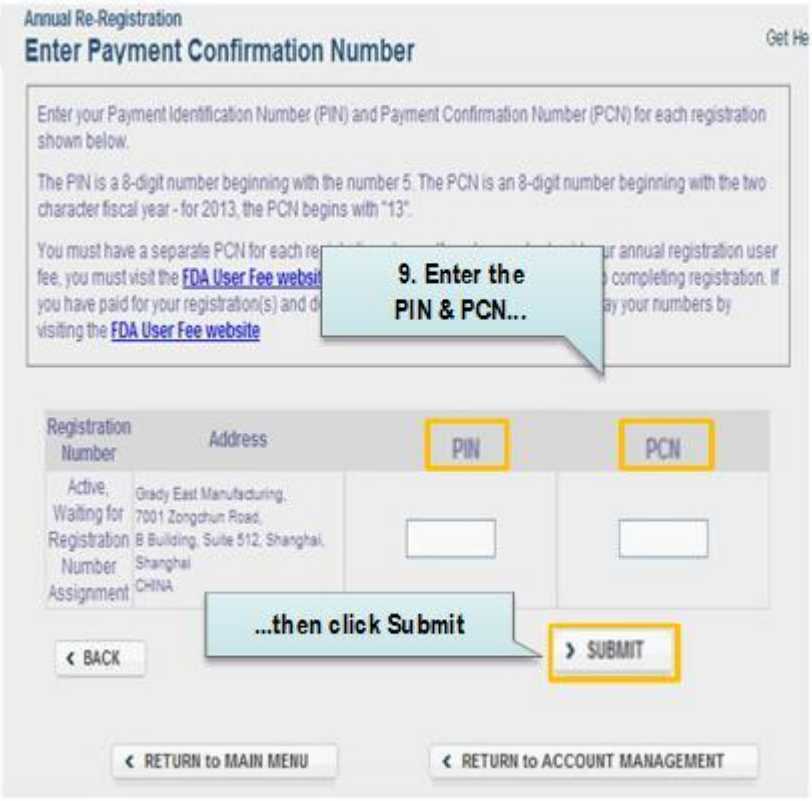
Certificate



Notes:

8. On the Review Registration Information page, scroll down to the Certification Statement. Review the statement and click the checkbox and then "Submit." If you get an error message, click the checkbox next to the statement before trying to resubmit.

Payment



Notes:

9. On the Enter Payment Confirmation Number page, enter the PIN & PCN. Note that you must have a unique PIN & PCN to register each facility. When you click Submit, print out a copy of the annual registration for your records.

Contact Information

Notes:

Please contact us if you have any questions about the re-registration process.